December 9, 2015

Amgen Submits Application In Europe To Expand Indication Of Kyprolis® (carfilzomib) For The Treatment Of Relapsed Multiple Myeloma

THOUSAND OAKS, Calif. (Dec 5, 2015) – Amgen (NASDAQ:AMGN) announced the submission to the European Medicines Agency (EMA) of a Variation to the Marketing Authorization Application (MAA) to expand the indication for Kyprolis® (carfilzomib) in combination with dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. The application is based on results from the Phase 3 head-to-head ENDEAVOR study in which patients with multiple myeloma treated with Kyprolis plus dexamethasone achieved superior progression-free survival (PFS) compared to those receiving Velcade® (bortezomib) plus dexamethasone.

For further information, visit the link below to the website for press release distributed by Amgen.

http://www.amgen.com/media/news-releases/2015/12/amgen-submits-application-in-europe-to-expand-indication-of-kyprolis-carfilzomib-for-the-treatment-of-relapsed-multiple-myeloma/

In Japan, ONO entered into an exclusive license agreement with Onyx, a subsidiary of Amgen, in September 2010 to develop and commercialize two compounds from Onyx's proteasome inhibitor development program, carfilzomib (for injection) and oprozomib (orally administered) for all oncology indications. ONO submitted Manufacturing and Marketing Approval Application for "carfilzomib for Injection (ONO-7057)", to seek an indication for relapsed or refractory multiple myeloma in August 2015.

Contact
ONO PHARMACEUTICAL CO., LTD.
Corporate Communications
public_relations@ono.co.jp